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Special 510(k) Device Modification:
EBI® XFIX® Vision® Fixation System

510(k) Summary

This 510(k) Summary for the EBI® XFIX® Vision® Fixation System is provided as required per Section 513(I)(3) of the Federal Food, Drug and Cosmetic Act.

1. **Sponsor:**
EBI, L.P.
100 Interpace Parkway
Parsippany, NJ 07054

Contact Person: Frederic Testa, RAC
Telephone: (973) 299-9300, ext.2208

Date Prepared: March 23, 2004

2. **Proprietary Name:** EBI® XFIX® Vision® Fixation System

Common Name: External Fixation Device

Classification Name: Single Multiple Component Metallic Bone Fixation Appliances and Accessories, 21 CFR 888.3030.

3. **Predicate or Legally Marketed Device:**

- EBI® XFIX® Vision® Fixation System (K993886, K011711, K014194, K033635)

4. **Description of Device:**

The System consists of external fixation components and implantable bone screws. The EBI® XFIX® Vision® Fixation System is utilized in the following manner: bone screws are inserted through the patient's skin and soft tissue, and into the bone. The fixator frame of the EBI® XFIX® Vision® Fixation System is attached to the shanks of the bone screws. This submission is for the additional rod sizes to the existing System. The intended use and fundamental scientific technology have not changed from the previously cleared submission.

5. **Intended Use:**

The EBI® XFIX® Vision® Fixation System is a unilateral external fixation device intended for use in the treatment of bone conditions including leg lengthening, osteotomies, arthrodesis, fracture fixation, and other bone conditions amenable to treatment by use of the external fixation modality.

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6. **Materials:**

The components of the System may be manufactured from materials such as Aluminum Alloy, Stainless Steel, Pyromet® 718, Carbon Fiber, and Titanium Alloy.

7. **Comparison of the technological characteristics of the device to predicate devices:**

The modified EBI® XFIX® Vision® Fixation System is substantially equivalent to the following predicate device:

EBI® XFIX® Vision® Fixation System (K993886, K011711, K014194, K033635)

- The additional EBI® XFIX® Vision® Fixation System components are fabricated from the same materials as the components of the currently marketed EBI® XFIX® Vision® Fixation System.
- The modified EBI XFIX® Vision® Fixation System and the currently marketed EBI® XFIX® Vision® Fixation System are both indicated for the treatment of bone conditions, including leg lengthening, osteotomies, arthrodesis, fracture fixation, and other bone conditions amenable to treatment by use of the external fixation modality.
- The bone screw clamps of the modified EBI® XFIX® Vision® Fixation System, like the bone screw clamps currently marketed in the EBI® XFIX® Vision® Fixation System, are designed for attachment to the bone screws.
- The modified EBI® XFIX® Vision® Fixation System like the currently marketed EBI® XFIX® Vision® Fixation System, is provided non-sterile.

There are no significant differences between the modified EBI® XFIX® Vision® Fixation System and the currently marketed EBI® XFIX® Vision® Fixation System. It is substantially equivalent* to the predicate device with regard to intended use, materials, and function.

*Any statement made in conjunction with this submission regarding a determination of substantial equivalence to any other product is intended only to relate to whether the product can be lawfully marketed without pre-market approval or reclassification and is not intended to be interpreted as an admission or any other type of evidence in patent infringement litigation. [Establishment Registration and Premarket Notification Procedures, Final Regulation, Preamble, August 23, 1977, FR 42520 (Docket No. 76N-0355.)]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 9 2004

Mr. Frederic Testa, RAC
Regulatory Affairs Specialist
EBI, L.P.
100 Interpace Parkway
Parsippany, New Jersey 07054

Re: K040833
Trade/Device Name: EBI® XFIX® Vision® Fixation System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: KTT
Dated: March 23, 2004
Received: March 31, 2004

Dear Mr. Testa:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known):

Device Name: EBI® XFIX® Vision® Fixation System

Indications For Use:

The EBI® XFIX® Vision® Fixation System is a unilateral external fixation device intended for use in the treatment of bone conditions including leg lengthening, osteotomies, arthrodesis, fracture fixation, and other bone conditions amenable to treatment by use of the external fixation modality.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use
(Optional Format 1-2-96)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K040833